FEB 2 0 2004

K033950

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared
December 1, 2003

2.0 Submitter
L.W.M. Heller
D.O.R.C. International b.v.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

3.0 Device Name
Proprietary Name: D.O.R.C. Vitrectomy Lens
Common Name(s): Vitrectomy Lens
Classification Name: Polymethylmethacrylate Diagnostic Contact Lens

4.0 Device Classification
HJK, Class II, 21 CFR 886.1385

5.0 Device Description
D.O.R.C. Vitrectomy Lens includes a variety of designs both sterile, single use, disposable vitrectomy lenses, as well as vitrectomy lenses intended to be reused which are sold non-sterile.

6.0 Intended Use
The Vitrectomy Lenses are intended to be used in conjunction with an operating microscope as a surgical optic to improve visualization of the ocular fundus, vitreous and retinal structures. Vitrectomy lenses are indicated for use during vitreoretinal surgical procedures.

7.0 Substantial Equivalence
The D.O.R.C. Vitrectomy Lenses are equivalent in design, materials, classification, intended use and indications to vitrectomy lenses marketed by Ocular Instruments Inc. cleared via 510(k) number K012096, 8/24/01.

	D.O.R.C. Vitrectomy Lens	**Ocular Instruments Inc. Vitrectomy Lens**
Materials	Silicone, glass, quartz	Silicone, glass, quartz
Design	Various designs including bioconcave, wideview field, flat lens, 20° and 30° prism lenses. Some designs may be used with a handle or sutured scleral ring.	Various designs including bioconcave, wideview field, flat lens, 20° and 30° prism lenses. Some designs may be used with a handle or sutured scleral ring.
Sterility	Sterile Disposable and Non-Sterile Reusable	Sterile Disposable and Non-Sterile Reusable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Dutch Ophthalmic Research Center
c/o Fran Carleton
Dutch Ophthalmic USA
One Little River Road
Kingston, NH 03848

Re: K033950
Trade/Device Name: D.O.R.C. Vitrectomy Lenses
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate Diagnostic Contact Lens
Regulatory Class: Class II
Product Code: HJK
Dated: December 11, 2003
Received: December 29, 2003

Dear Mr. Carleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K033950

Device Name: D.O.R.C. Vitrectomy Lens

Indications for Use:

The Vitrectomy Lenses are intended to be used in conjunction with an operating microscope as a surgical optic to improve visualization of the ocular fundus, vitreous and retinal structures. Vitrectomy lenses are indicated for use during vitreoretinal surgical procedures.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033950